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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/538,636

06/10/2005

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EXAMINER

BAUSCH, SARAE L

ART UNIT

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/538,636	<b>Applicant(s)</b> KOIZUMI ET AL.	
	<b>Examiner</b> SARAE BAUSCH	<b>Art Unit</b> 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 June 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-42 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-6, 14 (as it reads on SEQ ID No. 1) drawn to nucleic acids represented by SEQ ID No.1.

Group II, claim(s) 7-12, 14 (as it reads on SEQ ID No. 2) drawn to nucleic acids represented by SEQ ID No. 2.

Group III, claim(s) 13, drawn to method of detecting *V. cholerae* and *V. mimicus*.

Group IV, claim(s) 15-20, 28 (as it reads on SEQ ID No. 3), drawn to nucleic acids represented by SEQ ID No. 3.

Group V, claim(s) 21-26 and 28 (as it reads on SEQ ID No. 4), drawn to nucleic acids represented by SEQ ID No. 4.

Group VI, claim(s) 27, drawn to method of detecting *V. cholerae*.

Group VII, claim(s) 29-34, and 42 (as it reads on SEQ ID No. 5), drawn to nucleic acids represented by SEQ ID No. 5.

Group VIII, claim(s) 35-40 and 42 (as it reads on SEQ ID No. 6) drawn to nucleic acids represented by SEQ ID No. 6.

Group IX, claim 41, drawn to method of detecting *V. mimicus*.

2. The inventions listed as Groups I-IX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

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The special technical feature of group I is considered to be a fragment represented by SEQ ID No. 1. Brennan et al. (US Patent 5474796) teaches an array having every possible permutation of a 3 mer and 10mer oligonucleotide (see example 4, column 9 lines 15-60 and figure 1). Thus Brennan et al. teach a fragment that is represented by SEQ ID No. 1 (as well as SEQ ID No. 2-6). The special technical feature of group I is not a contribution over the prior art. Thus, the special technical feature linking the recited groups I-IX does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

Further Restriction Requirement

3. Applicant is required to elect one or a specific combination of positions as well as a specific primer or specific combination of primers. For example, if applicant elects group I, for claims 1-2 applicant is required to elect a specific combination of positions. For claims 5, applicant is required to elect a specific combination of primers. The claims are drawn to nucleic acid sequences and methods for detecting *V. cholerae* or *V. mimicus* in a sample. The claims are directed to numerous distinct products methods recited in the alternative. The language “one or more” requires that one, two, three or any number more up to the 28 recited positions and primers are detected within a target nucleic acid sample. For example, a nucleic acid fragment requiring position 21 of SEQ ID NO: 1 is distinct from a fragment requiring position 258 of SEQ ID No. 1 because the methods have a different mode of operation, do not overlap in scope, and they are not obvious variants of one another (see MPEP 806.05(j)).

The claims further encompass many subcombinations which are disclosed as usable together in a single combination and which are also separately usable. For example, consider the following combinations of “one or more” positions selected from those disclosed in SEQ ID NO: 1:

Subcombination (A): position 21 of SEQ ID No. 1

Subcombination (B): position 258 of SEQ ID No. 1

Combination (A+B): position 21 and 258 of SEQ ID No. 1

Each of the combinations of sequences are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct if they do not overlap in scope and are not obvious variants, and if it is shown that at least one subcombination is separately usable. In this case subcombinations (A) and (B) do not overlap in scope and there is no evidence on the record to suggest that they are obvious variants of one another. The subcombinations are separately usable as evidenced by their presentation in the alternative within the claims. Further, subcombination "A" has separate utility such as detecting the sequence, as a marker, for examples . So, subcombinations (A) and (B) are distinct. See MPEP § 806.05(d).

These subcombinations are also distinct from the combination which comprises them because the combination does not require the particulars of the subcombination as claimed to show novelty or unobviousness and the subcombinations have utility by themselves or in another combination. The fact that the claim encompasses an embodiment which relies on only subcombination (B) is evidence that the details of subcombination (A) are not required for patentability of the combination (A+B), and likewise, the fact that the claim encompasses an embodiment which relies on only subcombination (A) is evidence that the details of subcombination (B) are not required for patentability of subcombination (A+B). The fact that the claim encompasses embodiments which use only subcombination (A) or subcombination (B) is evidence that the subcombinations have utility by themselves.

This example particularly discusses only the combinations (A), (B) and (A+B), but the same analysis could be applied to each of the different subcombinations and combinations set forth in the instant claims.

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Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Each sequence must be searched by a separate query of the electronic databases. See MPEP 808.02(C). Therefore, a search for methods which use each sequence or each combination of sequences is not co-extensive with methods which use each other SEQUENCE or each other combination of sequences, and subsequently, the search and examination for every sequence and every combination of sequence poses an enormous and serious burden on the examiner.

Applicant is required to select a single invention, ie, a single sequence or a single combination of sequences required for the claimed method. The invention may be a single SEQUENCE, a combination of more than one sequence but less than all of the disclosed SEQUENCE or a combination of all possible claimed sequences. However, an election of a single invention, ie, a single position and primer or a single combination of positions within SEQ ID No. and primers is required. This restriction requirement is predicated on the fact that the methods which use different sequences or different combinations of sequences do not appear obvious over one another. Should applicant traverse on the ground that the different sequences or different combinations of sequences are not patentably distinct over each other, applicant should submit evident or identify such evidence now of record showing the inventions to be obvious variant over each other or clearly admit on the record that this is the case. In

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either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other inventions.

Applicant is also required to identify which claims read upon the elected invention.

The examiner has required restriction between subcombinations usable together. Where applicant elects a subcombination and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

4. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the



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application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarae Bausch whose telephone number is (571) 272-2912. The examiner can normally be reached on M-F 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Sarae Bausch/  
Primary Examiner, Art Unit 1634